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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,202	05/19/2006	Nathan Bryan Mantlo	X16094	2055
25885 7590 09/04/2007 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 09/04/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/580,202	Applicant(s) MANTLO ET AL.	
	Examiner Shawquia Young	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 9-69, 74-77 and 82-84 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,15,19,20,22,25,26,39,44,45,47,49,50,53-55,57,61,62 and 67-69.

DETAILED ACTION

Claims 1, 3, 9-69, 74-77, and 82-84 are currently pending in this application.

Applicants have cancelled claims 2, 4-8, 40, 70-73 and 78-81 and have withdrawn claims 1, 15, 19, 20, 22, 25, 26, 39, 44, 45, 47, 49, 50, 53, 54, 55, 57, 61, 62 and 67-69 in a preliminary amendment.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

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"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. **R1, R8, R9, R10, R11, R32, E, Y, X, U, V**, etc. and their widely divergent meanings, a precise listing of inventive groups cannot be made. *The following groups are exemplary:*

Group I claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 (in part), are drawn to a compound of formula (Ic) wherein: **R1** (attached to the bottom Nitrogen atom adjacent to C atom bonded to variable **U**) is phenyl optionally substituted with from one to three substituents independently selected from **R1'**; **R1', R26, R27, R28** and **R31** are independently selected from the group as defined in claim 3 excluding heteroaryl and heterocycloalkyl; **V** is C₀₋₈alkyl; **X** is selected from the group consisting of a single bond, O and S; **U** is as defined in claim 3; **Y** is selected from the group consisting of C, O and S; **E** is

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C(R3)(R4)A; **A** is as defined in claim 3; each **R⁷** is independently selected from the group consisting of hydrogen, C₁₋₆ haloalkyl, aryl C₀₋₄ alkyl and C₁₋₆ alkyl; **R3** is C₁₋₂ alkyl; **R4** is methyl; **R8** is selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ alkylenyl and halo; **R9** is as defined in claim 3 excluding heteroaryl; **R10**, **R11** are each as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R12'**, **R12''**, **R13'**, **R14'**, **R15'**, **R16'**, **R17'**, **R18'**, **R19'**, **R20'**, **R21'**, **R22'**, **R23'**, **R24'** and **R25'** are each independently selected from the group consisting of hydrogen, C₁₋₆ alkyl and aryl; **R30** is as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R32** is selected from the group consisting of a bond, hydrogen, halo, C₁₋₆ alkyl, C₁₋₆ haloalkyl and C₁₋₆ alkyloxo; and dashed bond is optionally a bond to form a double bond at the indicated position, classified in various subclasses in class 548.

Group II claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 (in part), are drawn to a compound of formula (Ic) wherein: **R1** (attached to the bottom Nitrogen atom adjacent to C atom bonded to variable **U**) is furanyl optionally substituted with from one to three substituents independently selected from **R1'**; **R1'**, **R26**, **R27**, **R28** and **R31** are independently selected from the group as defined in claim 3 excluding heteroaryl and heterocycloalkyl; **V** is C₀₋₈alkyl; **X** is selected from the group consisting of a single bond, O and S; **U** is as defined in claim 3; **Y** is selected from the group consisting of C, O and S; **E** is **C(R3)(R4)A**; **A** is as defined in claim 3; each **R⁷** is independently selected from the group consisting of hydrogen, C₁₋₆ haloalkyl, aryl C₀₋₄ alkyl and C₁₋₆ alkyl; **R3** is C₁₋₂ alkyl; **R4** is methyl; **R8** is selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄

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alkylenyl and halo; **R9** is as defined in claim 3 excluding heteroaryl; **R10**, **R11** are each as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R12'**, **R12''**, **R13'**, **R14'**, **R15'**, **R16'**, **R17'**, **R18'**, **R19'**, **R20'**, **R21'**, **R22'**, **R23'**, **R24'** and **R25'** are each independently selected from the group consisting of hydrogen, C₁₋₆ alkyl and aryl; **R30** is as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R32** is selected from the group consisting of a bond, hydrogen, halo, C₁₋₆ alkyl, C₁₋₆ haloalkyl and C₁₋₆ alkyloxo; and dashed bond is optionally a bond to form a double bond at the indicated position, classified in various subclasses in class 548.

Group III claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 (in part), are drawn to a compound of formula (Ic) wherein: **R1** (attached to the bottom Nitrogen atom adjacent to C atom bonded to variable **U**) is thienyl optionally substituted with from one to three substituents independently selected from **R1'**; **R1'**, **R26**, **R27**, **R28** and **R31** are independently selected from the group as defined in claim 3 excluding heteroaryl and heterocycloalkyl; **V** is C₀₋₈alkyl; **X** is selected from the group consisting of a single bond, O and S; **U** is as defined in claim 3; **Y** is selected from the group consisting of C, O and S; **E** is C(**R3**)(**R4**)**A**; **A** is as defined in claim 3; each **R⁷** is independently selected from the group consisting of hydrogen, C₁₋₆ haloalkyl, aryl C₀₋₄ alkyl and C₁₋₆ alkyl; **R3** is C₁₋₂ alkyl; **R4** is methyl; **R8** is selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ alkylenyl and halo; **R9** is as defined in claim 3 excluding heteroaryl; **R10**, **R11** are each as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R12'**, **R12''**, **R13'**, **R14'**, **R15'**, **R16'**, **R17'**, **R18'**, **R19'**, **R20'**, **R21'**, **R22'**, **R23'**, **R24'** and **R25'** are each independently

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selected from the group consisting of hydrogen, C₁₋₆ alkyl and aryl; **R30** is as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R32** is selected from the group consisting of a bond, hydrogen, halo, C₁₋₆ alkyl, C₁₋₆ haloalkyl and C₁₋₆ alkyloxo; and dashed bond is optionally a bond to form a double bond at the indicated position, classified in various subclasses in class 548.

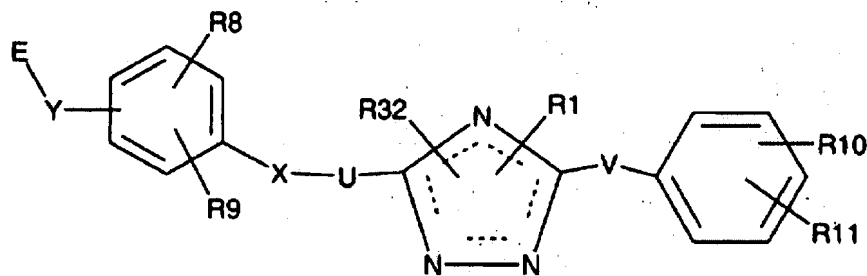
Group IV claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 (in part), are drawn to a compound of formula (Ic) wherein: **R1** (attached to the bottom Nitrogen atom adjacent to C atom bonded to variable **U**) is pyridyl optionally substituted with from one to three substituents independently selected from **R1'**; **R1'**, **R26**, **R27**, **R28** and **R31** are independently selected from the group as defined in claim 3 excluding heteroaryl and heterocycloalkyl; **V** is C₀₋₈alkyl; **X** is selected from the group consisting of a single bond, O and S; **U** is as defined in claim 3; **Y** is selected from the group consisting of C, O and S; **E** is C(**R3**)(**R4**)**A**; **A** is as defined in claim 3; each **R⁷** is independently selected from the group consisting of hydrogen, C₁₋₆ haloalkyl, aryl C₀₋₄ alkyl and C₁₋₆ alkyl; **R3** is C₁₋₂' alkyl; **R4** is methyl; **R8** is selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ alkylenyl and halo; **R9** is as defined in claim 3 excluding heteroaryl; **R10**, **R11** are each as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R12'**, **R12''**, **R13'**, **R14'**, **R15'**, **R16'**, **R17'**, **R18'**, **R19'**, **R20'**, **R21'**, **R22'**, **R23'**, **R24'** and **R25'** are each independently selected from the group consisting of hydrogen, C₁₋₆ alkyl and aryl; **R30** is as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R32** is selected from the group consisting of a bond, hydrogen, halo, C₁₋₆ alkyl, C₁₋₆ haloalkyl and C₁₋₆ alkyloxo; and dashed bond is

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optionally a bond to form a double bond at the indicated position, classified in various subclasses in class 546.

Group V claim(s) 3, 9-14, 16-19, 20, 21, 23, 24, 27-38, 40-43, 46, 48, 51, 52, 56, 58-60, 63-66, 74-77, and 82-84 (in part), are drawn to a compound of formula (Ic) wherein: **R1** (attached to the bottom Nitrogen atom adjacent to C atom bonded to variable **U**) is pyrimidyl optionally substituted with from one to three substituents independently selected from **R1'**; **R1'**, **R26**, **R27**, **R28** and **R31** are independently selected from the group as defined in claim 3 excluding heteroaryl and heterocycloalkyl; **V** is C₀₋₈alkyl; **X** is selected from the group consisting of a single bond, O and S; **U** is as defined in claim 3; **Y** is selected from the group consisting of C, O and S; **E** is C(**R3**)(**R4**)**A**; **A** is as defined in claim 3; each **R⁷** is independently selected from the group consisting of hydrogen, C₁₋₆ haloalkyl, aryl C₀₋₄ alkyl and C₁₋₆ alkyl; **R3** is C₁₋₂ alkyl; **R4** is methyl; **R8** is selected from the group consisting of hydrogen, C₁₋₄ alkyl, C₁₋₄ alkylenyl and halo; **R9** is as defined in claim 3 excluding heteroaryl; **R10**, **R11** are each as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R12'**, **R12''**, **R13'**, **R14'**, **R15'**, **R16'**, **R17'**, **R18'**, **R19'**, **R20'**, **R21'**, **R22'**, **R23'**, **R24'** and **R25'** are each independently selected from the group consisting of hydrogen, C₁₋₆ alkyl and aryl; **R30** is as defined in claim 3 excluding heteroaryl-C₀₋₄ alkyl; **R32** is selected from the group consisting of a bond, hydrogen, halo, C₁₋₆ alkyl, C₁₋₆ haloalkyl and C₁₋₆ alkyloxo; and dashed bond is optionally a bond to form a double bond at the indicated position, classified in various subclasses in class 544.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, **this list is not exhausted**, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. **If applicant is unable to elect a single invention, applicant may instead choose to elect a specific compound and examiner will attempt to group it.** The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art (See, XP-002322768, for example). The compounds claimed contain



, which does not define a contribution over the prior art. The compounds vary in classification and when taken as a whole result in vastly different compounds. Accordingly, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be

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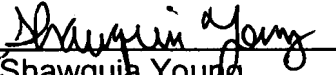
traversed (37 CFR 1.143).


Telephone Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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